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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,952	12/13/2001	Andrew G. Plaut	00398/502003	2691

21559 7590 03/26/2003

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EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	7

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,952	PLAUT ET AL.	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9 are drawn to a method for substantially reducing the pathogenicity of an infectious agent comprising a naturally occurring lactoferrin, classified in class 435, subclass 262.

II. Claims 10-11 are drawn to a method for substantially reducing the pathogenicity of an infectious agent comprising a fragment of lactoferrin, classified in class 435, subclass 262.5.

III. Claims 12-13 are drawn to a method of inhibiting microbial colonization in a mammal by administering naturally occurring lactoferrin, classified in class 424, subclass 9.1.

IV. Claims 14-15 are drawn to drawn to a method of inhibiting microbial colonization in a mammal by administering a fragment of lactoferrin, classified in class 424, subclass 9.2.

V. Claim 16 is drawn to a method for substantially inactivating an infectious agent by contacting a naturally occurring lactoferrin, classified in class 435, subclass 236.

VI. Claims 17-21 are drawn to a method for substantially inactivating an infectious agent by contacting a fragment of lactoferrin, classified in class 435, subclass 238.

VII. Claims 22-24 are drawn to an antimicrobial pharmaceutical composition comprising a naturally occurring lactoferrin, classified in class 424, subclass 184.1.

VIII. Claims 25-26 are drawn to an antimicrobial pharmaceutical composition comprising a fragment of lactoferrin, classified in class 424, subclass 200.1.

IX. Claims 27-29 and 32-34 are drawn to a method for producing an attenuated vaccine and the attenuated vaccine comprising an inactivated lactoferrin, classified in class 424, subclass 234.1.

X. Claims 20-31 and 35-36 are drawn to a method for producing an attenuated vaccine and the attenuated vaccine comprising a fragment of lactoferrin, classified in class 424, subclass 278.1.

XI. Claim 37 is drawn to a pure peptide consisting of the N-terminal lobe of lactoferrin, classified in class 530, subclass 395.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and any of II-VI, IX and X are related as methods. The methods are distinct as claimed because they have different methods with different method steps; different functions and the effects have different final outcomes. Although some groups may share steps it is noted that the groups use different reagents. For instance both groups I and II are drawn to a method for substantially reducing the pathogenicity of an infectious agent, however group I comprises using a naturally occurring lactoferrin while

group II uses a fragment of lactoferrin. The naturally occurring lactoferrin and lactoferrin fragments have substantial structural features disclosed as being essential to that utility. The naturally occurring lactoferrin and lactoferrin fragments differ in both structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility. Each group further requires additional unrelated agents, produce different effects and have different functions when compared to the other groups. Therefore, the methods of the inventions are distinct as claimed.

Inventions VII and either VIII or XI are related as different products. The products are distinct as claimed because they have different structures and different uses. Groups VII and VIII are drawn to antimicrobial composition comprised of either a naturally occurring lactoferrin or fragment of lactoferrin while group XI is drawn to a peptide. Each group has a different function, effect and is capable of use without the other. For instance, the peptide product of Group XI be used in a method of detection as opposed to the products of groups VII or VIII that cannot. Each group has a different structure, produces different effects and has different functions when compared to the other group. Therefore, the products of the inventions are distinct as claimed.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-XI, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
March 24, 2003

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600